

## **REMARKS**

This Amendment is made in response to the final Office Action dated January 20, 2010. Claims 26-30, 32-34 and 47-65 are pending in this application. By this Amendment, claims 26 and 47 have been amended to more clearly define the presently claimed invention. New claims 66-76 are being presented for consideration. Favorable reconsideration of all of the pending claims is respectfully requested in view of the remarks below.

### **Interview Summary**

On April 13, 2010, Examiner Houston conducted a telephonic interview with Applicant's undersigned attorney. Applicant's in-house attorney, Jonathan Feuchtwang, also took part in the telephonic interview. Examiner Houston and Applicant's undersigned attorney discussed the Examiner's rejection of the claims under 35 U.S.C. § 103(a) as being unpatentable over U. S. Patent No. 5,792,144 to Fischell (the "Fischell patent") in view of U. S. Patent No. 5,545,138 to Fugoso (the "Fugoso patent"). The structure of both the catheter disclosed in the Fischell patent and Fugoso patent was discussed in great detail. The Examiner's rejection of the claims under 35 U.S.C. § 112 was also discussed. No agreement was reached regarding the patentability of the claims in view of the cited art.

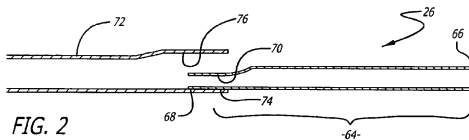
### **Claims Rejected under 35 U.S.C. § 112**

Claims 26-30, 32-34 and 47-65 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner takes the position that the limitation previously recited in the claims, namely, "to allow the guide wire to exit the proximal end of the guide wire receiving member and an opening formed at the proximal end of the intermediate portion of the outer catheter member *without bending*" does not find support within the disclosure of the application. Applicants have amended all of the claims to eliminate the phrase "*without bending*" but

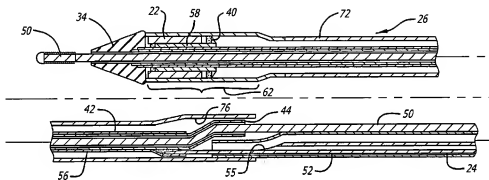
wish to make the following remarks for the record. FIG. 1 of the present application does show that the guide wire does not need to bend once outside of the outer catheter member. This feature, which was previously recited in the claims, relates to the structure of the guide wire **once it has exited** the outer catheter member. Reference is made to FIG. 1 of the pending application, reproduced below, which shows that once the guide wire extends out of the outer catheter member, it will remain straight as it lies adjacent to the proximal portion of the outer catheter member during usage. This is in direct contrast to the bending that the guide wire must make once outside of the catheter disclosed in the Fischell patent cited by the Examiner and discussed in greater detail below.

**Claims Rejected under 35 U.S.C. § 103**

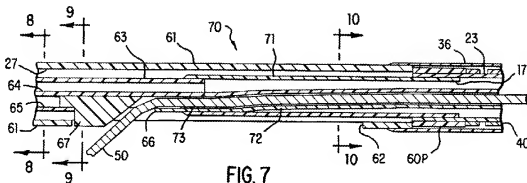
Claims 26-30, 32, 47-52 and 54-65 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Fischell patent in view of the Fugoso patent. As is noted above, independent claims 26 and 47 have been amended to more clearly define the presently claimed invention. These claims recite a structure in which the proximal end of the intermediate portion has an outer diameter which is larger than the diameter of the distal end of the proximal outer member. The larger diameter of the intermediate and the smaller diameter of the proximal portion create a transition region in which a passage is created between these two components. FIG. 2 of the present application is reproduced below for the convenience of the reader. FIG. 2 shows one particular



embodiment of the outer catheter member 26 covered by the present claims. As can be seen in FIG. 2, the diameter of the proximal end 74 of the intermediate portion 72 is much larger than the diameter of the distal end 68 of the proximal portion 64. As a result, a passage (referred to as a space 76 in the application) is created which allows the guide wire (shown below in FIG. 1) to extend therethrough and out of the outer catheter member 26. The Fischell patent simply does not disclose such a structure, as is acknowledged by the Examiner in the final Office Action. As can be seen in FIG. 1 of the present application (reproduced below), once the guide wire 50 extends out of the passage 76 of outer catheter member 26, it lies straight and adjacent to the proximal portion 64 and does not need to bend.



In contrast, as can be seen from the Fischell catheter, namely, in Figure 7 reproduced below, the guide wire 50 must bend once outside of the guide wire receiving



portion of the catheter. It is noted that the guide wire 50 in FIG. 7 above does not appear to bend as it exits the slot 62 cut into the side wall of the outer catheter. However, when placed within a patient's vasculature, this guide wire 50 must bend in order to follow the axis of the catheter and body lumen. When the Fischell catheter is being advanced through the patient's anatomy, the bend in the guide wire will be continuously maintained between the outer surface of the catheter and the wall of the patient's anatomy, which can possibly slow the advancement through the patient's anatomy. Moreover, the Fischell catheter must include an elongate slot 62 which must be accurately cut into the outer member (sidewall) so that the outer member can be retracted proximally to deploy the stent. The Fischell patent also requires the use and formation of a "key" 67 on the inner catheter member which causes the guide wire 50 to first bend to exit the side slot 62 of the catheter. Again, once the guide wire 50 extends out of this slot 62, it must again significantly bend to follow the axis of the catheter and body vessel.

The presently claimed invention allows the guide wire receiving member 42 to slide within the passage formed on the outer catheter member thus eliminating the need for the formation of an accurate elongated slot 62 and key 67. Moreover, as is shown above in FIG. 1, the guide wire 50 exits the rapid-exchange portion of the presently claimed invention without the need to bend once **outside the catheter**. In this regard, a guide wire used in accordance with the presently claimed invention may move more smoothly through the rapid-exchange portion of the catheter as it is being delivered through the patient's anatomy.

Applicants note that the Examiner relies on the Fugoso patent to supply the structure which the Examiner admits is not shown in the Fischell patent. However, Applicants respectfully note that the Fugoso patent does not disclose an outer catheter member, as is recited in the pending claims. The Fugoso patent, rather, is directed to a catheter structure which actually defines an inner catheter member. Figure 1 of the

Fugoso patent is reproduced below for the convenience of the reader. As can be seen, the catheter includes a guide wire lumen shaft 1 (the "guide wire receiving member") along

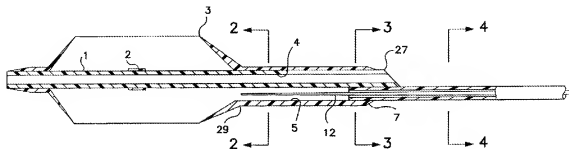


FIG. 1

with a balloon 3 (which could be used as the "distal mounting portion"). The guide wire lumen shaft 1 includes a proximal end 27 which is spaced apart from the proximal end (not shown in FIG. 1) of the inner catheter shaft 6.

A comparison of the inner catheter member shown in the Fischell patent with the Fugoso catheter shows the same basic structure. Figure 7 of the Fischell patent (reproduced above) shows the use of a balloon 23 as the "distal mounting portion" and an inner shaft 72 used as the "guide wire receiving member." The proximal end of the inner shaft 72 in the Fischell patent also includes a port 66 found at the very end of the shaft. The inner shaft 72 of the Fischell catheter has the same basic structure as the guide wire lumen shaft 1 shown in the Fugoso patent. The Fischell patent also includes a single lumen (the balloon access lumen 64) which performs the same function as the shaft 6 in the Fugoso patent, namely, a fluid conduit for supplying balloon inflation fluid to the balloon. Accordingly, the basic structure shown in the inner catheter of the Fischell catheter is shown in the catheter of the Fugoso patent.

It is important to note that the catheter disclosed in the Fugoso patent does not constitute an outer catheter member, or functions in any reasonable manner as an outer catheter member, in accordance with the presently claimed invention, since the Fugoso

patent does not teach the use of a medical device, such as a stent, which can be carried on the balloon 3. Accordingly, the Fugoso patent lacks the teaching of an outer catheter member which covers an inner catheter member. Accordingly, its disclosure of an inner catheter member does not serve as a teaching for the structure of the outer catheter member. For these reasons, Applicants strongly disagree with the Examiner's position that one skilled in the art would simply incorporate the structure of the Fugoso patent into the catheter structure disclosed in the Fischell patent to create the claimed invention. Applicants submit that one skilled in the art, in viewing both the Fischell patent and the Fugoso patent, would readily recognize that the same basic catheter structure is shown in both these patents. Therefore, if one skilled in the art incorporated the Fugoso catheter into the Fischell catheter, the same outer catheter shown in the Fischell patent would be utilized. One skilled in the art would still utilize the key 67 and elongated slot 62, as taught by Fischell, in creating the outer sheath. There is no teaching in the Fugoso patent which modifies the teachings of the Fischell patent. Moreover, one skilled in the art would have no reason to transform the balloon catheter of Fugoso into an outer catheter member. Rather, one skilled in the art might recognize that the Fugoso patent utilizes a stiffening wire 12 in the fluid delivery lumen of the shaft 6. In combining these references, one skilled in the art would recognize that the Fischell fluid delivery shaft 64 also could be reinforced by such a stiffening shaft. Accordingly, Applicants respectfully submit that if one skilled in the art would simply incorporate the Fugoso balloon catheter into the Fischell design, the outer catheter member disclosed in the Fischell patent would still be used. Accordingly, Applicants respectfully submit that the correct combination of the Fischell patent with the Fugoso patent would not create the structure recited in the presently claimed invention. Applicants request the Examiner to withdraw all obviousness rejections raised against the claims at issue.

Claims 63-65 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Fischell patent in view of the Fugoso patent and in further view of U. S. Patent

Publication No. 2003/0028235 to McIntoish (the "McIntoish publication"). Claims 33, 34 and 53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Fischell patent in view of the Fugoso patent and in further view of U. S. Patent No. 6,736,839 to Cummings (the "Cummings patent"). Applicants note that the combination of the Fischell patent with the Fugoso patent fails to create the basic structure recited in the rejected claims. The McIntoish publication and the Cummings patent fail to address the structure which is lacking from the Fischell/Fugoso combination. Applicants respectfully request the Examiner to withdraw the obviousness rejections raised against these claims as well.

In view of the foregoing, it is respectively urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Please charge any additional fee or credit any overpayment to our Deposit Account No. 06-2425.

Respectfully submitted,  
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